IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

FOGE, McKEEVER LLC; TODD M. ROONEY; and ELDON S. THOMPSON,	)	
Plaintiffs,	)	
v.	)	No.: 2:20-cv-01462-RJC
ZOETIS INC.,	)	
Defendant.	)	

OPINION

Robert J. Colville, United States District Judge.

Presently pending before the Court is a Motion to Dismiss Plaintiffs' Second Amended Complaint for Failure to State a Claim filed on behalf of Defendant Zoetis Inc. ("Zoetis") (ECF No. 23). The matter has been fully briefed and is ripe for disposition.

I. Background and Factual Allegations

This products liability action was brought by Plaintiffs Foge, McKeever LLC (hereinafter "FML"), Todd M. Rooney and Eldon S. Thompson (collectively "Owners") as a result of the sudden death of their filly racehorse after receiving injections of a drug developed and manufactured by defendant Zoetis Inc. On September 30, 2021, the Court granted the first motion to dismiss in this matter, dismissing Counts I, II, III, VII, IX and X of the ten-count Amended Complaint, without prejudice, and dismissing Counts IV, V, VI and VIII[1] of the Amended complaint with prejudice. On October 22, 2021, Plaintiffs filed a six-count Second Amended Complaint ("SAC"). (ECF No. 22).

[1] These counts alleged strict liability and implied warranty of merchantability.

The allegations in the SAC are as follows. Plaintiffs owned a 3-year old Standardbred filly known as Saratoga Gia ("SG"), at all relevant times stabled at the Meadows Racetrack located in Washington County, Pennsylvania. (SAC ¶ 9). On or about April 7, 2020, via an equine veterinarian, SG received an injection of Excede (ceftiofur crystalline-free acid) manufactured and distributed by defendant Zoetis to address a minor puncture wound. (SAC ¶ 10). The Owners' equine veterinarians relied upon representations made by Zoetis concerning the efficacy and safety of Excede in using Excede, including the inserts and warnings, including the lack thereof, provided with Excede. (SAC ¶ 11). The warnings included with the Excede used in this matter failed to inform veterinarians of the risk of death--unlike later changes to the inserts and warnings that acknowledged that deaths in horses had occurred. (SAC ¶ 12).

On or about April 11, 2020, per Zoetis' specific recommendations, SG was administered a second dosage of Excede via an equine veterinarian. (SAC ¶ 13). Almost immediately after the second administration of Excede, SG experienced a severe reaction to the drug, causing her to collapse to the floor of the stall and never get up. (SAC ¶ 14). Due to the extreme distress caused by the administration of Excede, SG was provided with continuous veterinary care up to and including her transport on April 13, 2020, to the Galbreath Equine Center, of the Ohio State University ("OSU"), in Columbus, Ohio, for additional emergency treatment. (SAC ¶ 15). Despite the emergency treatment, on April 15, 2020, SG died while under the care of OSU; SG died as a result of the administration of Excede, as directed. (SAC ¶ 16). The Owners notified Zoetis of SG's death caused by the Excede injections. (SAC ¶ 17). Prior to the Excede injections, SG was a promising and successful racehorse. (SAC ¶ 18).

Upon information and belief, Zoetis is acutely aware of similar adverse equine reactions to the injection of Excede in horses, but willfully, intentionally, maliciously and

negligently ignored the risks associated with injections of the drug and failed to adequately warn of those dangers. (SAC ¶ 19). Numerous other similar adverse reactions, including those with fatal outcomes, have occurred throughout the United States and elsewhere, and have been reported to Zoetis since at least 2012 and continuing through 2020. (SAC ¶ 20). Upon information and belief, from 2010 through at least 2020, nearly 600 adverse reaction reports were made by Zoetis to the Federal Drug Administration ("FDA") for Excede reactions experienced by horses in the United States. (SAC ¶ 21). Zoetis was fully aware that adverse reactions to the administration of Excede have included fatal reactions, internal hemorrhaging, anaphylaxis, and other systemic-type reactions. (SAC ¶ 22). In many of these instances, the affected horses were provided with extensive and expensive veterinary care and treatment, and the owners of the animals have absorbed veterinary costs as well as the diminished or ruined value associated with the horses who have died. In the case of SG, veterinary bills, other expenses and lost income (including, without limitation, lost breeding income) exceed $1.8 million dollars. (SAC ¶ 23). Upon information and belief, many of the horses who have suffered adverse reactions to the administration of Excede are performance animals. (SAC ¶ 24).

It is further alleged that Zoetis was aware of the adverse reactions to Excede, and the resulting veterinary costs and diminished or eliminated value of the afflicted horses. (SAC ¶ 25). Despite its knowledge of the severely debilitating and/or fatal reactions to the administration of Excede, Zoetis has neither disclosed nor adequately warned of Excede's danger to horses and has refused to adequately revise its warning label and prescribing information to reflect the significant negative effects of Excede. As a result, consumers, including the Owners, and treating veterinarians are left with no way of knowing of the considerable risks associated with the administration of Excede. (SAC ¶ 26). Had the Owners' equine veterinarians been adequately

warned of Excede's dangers they would not have used Excede on SG and recommended a different course of treatment. (SAC ¶ 27). The Owners' equine veterinarians have ceased using Excede due to its dangerous propensities. (SAC ¶ 28).

Excede is an antibiotic expressly marketed as treating equine infections with a "two dose, one solution" treatment for ill horses. (SAC ¶ 29). Zoetis further markets Excede as doing in 2 doses what would otherwise take 10. (SAC ¶ 30). Excede is also prescribed by veterinarians for off-label uses and Zoetis is well-aware of such usage and does not discourage such usage. (SAC ¶ 31). Indeed, most antibiotics prescribed by equine veterinarians are for off-label or extra-label use, which is permissible under federal law. (SAC ¶ 32).

Zoetis was aware that equine veterinarians used Excede off-label for treating conditions including the type of condition SG was being treated for, and that some horses experience the same type of adverse reaction that SG suffered as a result of the off-label use of Excede. (SAC ¶ 33). At all times relevant, Zoetis was well aware of the dangers posed by Excede when used in both on and off-label manners. (SAC ¶ 34). The warning contained on the Excede box in question reads, in part, "Not for use in humans. Keep this and all drugs out of reach of children." (SAC ¶ 35). That warning was also contained on the insert provided with the product and on the actual label of the bottle of Excede (SAC ¶ 36). The warning on the Excede bottle in question and with the inserts provided therein did not warn of the possibility of death when properly used (SAC ¶ 37). The 2013 insert that Excede provided with the product also set forth a section on Adverse Reactions, including injection site swelling, adverse reactions reported in a field study safety analysis, the statistics of edema reported in horses treated with Excede, other side effects, as well as how quickly reactions and side effects were resolved. (SAC ¶ 38). Notably, Zoetis failed to disclose that since FDA approval there have been approximately 600 adverse reactions

reported, with many including severe reactions and death. (SAC ¶ 39). The 2013 insert provided with the EXCEDE bottle used herein also set forth warnings as to the use of antibacterial drugs and certain other precautions. (SAC ¶ 40). Zoetis failed to include in either of the Antibacterial Warning or Precautions sections of its label any suggestion that proper use of Excede could result in death of the horse. (SAC ¶ 41). The 2013 Excede insert stated that a target animal safety (TAS) study and a pharmacokinetic (PK) study were conducted to assess the safety of Excede in horses, describing adverse reactions observed in those studies. (SAC ¶ 42). Notably absent from this warning is any suggestion of death as a negative reaction. (SAC ¶ 43).

A subsequent June 2020 insert (not provided with the Excede bottle used in this matter) in contrast, states, inter alia,[2] "[i]mmediate onset of seizures or collapse have been reported following Excede administration." (SAC ¶ 44). The June 2020 Post Approval Experience insert section (not provided with the product used herein) outlines other post-approval experience to include, inter alia: "In some cases, death has been reported as an outcome of the adverse events listed above. Sudden death (within minutes), or the immediate onset of seizures or collapse, followed by death or euthanasia, have been reported." (SAC ¶ 45). Despite having knowledge of such adverse reactions, Zoetis continued to sell Excede without the updated and revised warnings--including the product herein. (SAC ¶ 46).

Excede allegedly works through an extended release formulation, which, upon gaining FDA approval in 2010, Zoetis touted as a "true innovation." (SAC ¶ 47). Because of Excede's extended release formulation, Zoetis claims that its treatment of horses is easier and more effective because it allows owners and veterinarians to administer treatment with less stress to

[2] It further provides: "Due to the extended exposure in horses, based on the drug's pharmacokinetic properties, adverse reactions may require prolonged care. EXCEDE is slowly eliminated from the body, with approximately 17 days needed to eliminate 97% of the dose from the body. Animals experiencing adverse reactions may need to be monitored for this duration of time."

the animal. (SAC ¶ 48). Excede is extensively promoted and marketed for use with stabled animals, such as SG. (SAC ¶ 49). For performance horses such as SG, administration of a 10-day course of nonextended release antibiotics is a relatively easy task that has been accomplished in the horse industry for many decades. (SAC ¶ 50).

Zoetis manufactures a non-extended release injectable ceftiofur antibiotic for equines called Naxcel, which has been safely used in horses for decades. (SAC ¶ 51). Upon information and belief, the use of Naxcel has not resulted in the type of severe reactions caused by Excede. (SAC ¶ 52). The only significant difference between Naxcel and Excede is the extended-release delivery system found in Excede, which was designed by Zoetis utilizing a caprylic acid and cottonseed oil-based suspension. (SAC ¶ 53). Cottonseed oil is not used as a suspension in other regularly used, approved equine medications. (SAC ¶ 54). Cottonseed oil that is not refined or is improperly refined contains substances that are toxic to horses. (SAC ¶ 55).

It is further alleged that despite viable alternatives, and the known risks regarding the negative post-approval experiences suffered by, at least, hundreds of horses, Zoetis has willfully, intentionally, maliciously, and negligently refused to make alterations to Excede's label to adequately warn consumers of the dangers of Excede and continues to extensively market the product as being superior to traditional courses of antibiotic treatment for injured horses. (SAC ¶ 56).

Plaintiff's Second Amended Complaint contains six Pennsylvania state-law causes of action, specifically claims for negligence for failure to warn, defective design and manufacturing defect (Counts I-III, respectively), breach of express warranty (Count IV), fraudulent misrepresentation and concealment (Count V), and negligent misrepresentation (Count VI) against Zoetis. They claim entitlement to actual, compensatory, consequential and punitive

damages as a result of Zoetis' allegedly defective design and manufacture of Excede. (SAC at ¶ 22).

II. Standard of Review

A motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the complaint. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). In deciding a motion to dismiss, the court is not opining on whether the plaintiff will likely prevail on the merits; rather, when considering a motion to dismiss, the court accepts as true all well-pled factual allegations in the complaint and views them in a light most favorable to the plaintiff. *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002). While a complaint does not need detailed factual allegations to survive a Rule 12(b)(6) motion to dismiss, a complaint must provide more than labels and conclusions. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A "formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). The Supreme Court of the United States has explained:

> The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Id. (quoting *Twombly*, 550 U.S. at 556) (internal citations omitted).

III. Discussion

At the outset, we note that Zoetis has not moved to dismiss Count I, the claim for negligent failure to warn.

A. Counts II and II: Negligence

In Counts II and III, Plaintiffs assert products liability claims premised on negligent defective design and negligent manufacturing defect. Defendant moves to dismiss these claims, alleging Plaintiffs have failed to allege facts with sufficient plausibility. In products liability claims sounding in negligence, Pennsylvania courts follow the Restatement (Second) of Torts. *Smith v. Howmedica Osteonics Corp.,* 251 F. Supp. 3d 844, 852–53 (E.D. Pa. 2017). Manufacturing defects are governed by Section 395 and design defects are governed by Section 398. *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434, 445 n.13 (2014) ("[T]his Court has rather roundly endorsed the substantive principles reflected in both Sections 395 and 398...as having been 'adopted in practically all jurisdictions.'").

1. Count II: Negligent Defective Design

To plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design. *Smith*, 251 F. Supp. 3d at 854. Here, Defendant moves to dismiss this claim on the grounds that the allegations in Plaintiffs' SAC fail to identify any specific design defect or available reasonable alternative.

The SAC includes the following allegations, as to Count II:

> 50. For performance horses such as SG, administration of a 10-day course of non-extended release antibiotics is a relatively easy task that has been accomplished in the horse industry for many decades.
> 51. Zoetis manufactures a non-extended release injectable ceftiofur antibiotic for equines called Naxcel, which has been safely used in horses for decades.

52. Upon information and belief, the use of Naxcel has not resulted in the type of severe reactions caused by EXCEDE.
53. The only significant difference between Naxcel and EXCEDE is the extended release delivery system found in EXCEDE, which was designed by Zoetis utilizing a caprylic acid and cottonseed oil-based suspension.
54. Cottonseed oil is not used as a suspension in other regularly used, approved equine medications.
55. Cottonseed oil that is not refined or is improperly refined contains substances that are toxic to horse.

* * *

76. The EXCEDE antibiotic extended release formulation is unreasonably dangerous because it is defectively designed.
77. In this regard, Zoetis uses cottonseed oil in its design of EXCEDE.
78. As noted, cottonseed oil is not used as a suspension in other regularly used, approved equine medications.
79. Cottonseed oil that is not refined or is improperly refined contains substances that are toxic to horse.
80. EXCEDE even when used as recommended and with appropriate warnings is defective and unreasonably dangerous because it is defectively designed with cottonseed oil as a
suspension device.
81. As noted, an existing viable alternative treatment, such as Naxcel, would have reduced or eliminated the risk of injury to SG.

* * *

87. Zoetis continues to market its dangerous antibiotic despite the fact that there are safer and less expensive alternatives available, such as Naxcel.
88. Existing viable alternative treatments would have reduced or eliminated the risk of injury to SG.

We find that Plaintiffs' allegations that Zoetis was negligent in the design contain the requisite specificity as to why the design was flawed and that a better alternative was available. Generally, conclusory allegations that a product was negligently designed are not, on their own, sufficient to plead a viable claim. *See, e.g., Smith*, 251 F. Supp. 3d at 854 (dismissing negligent design claim where "[t]he only explicit reference to the product's design is the conclusory allegation that [d]efendants were negligent in such design"). However, to meet the requirement here, a plaintiff must do more than "baldly stat[e] that there are safer alternatives"; they must provide factual support demonstrating those alternatives exist. See *Salvio*, 810 F. Supp. 2d at 754

(citation omitted); *see also McGrain v. C.R. Bard, Inc.,* No. 21-1539, 551 F. Supp. 3d 529, 542-43 (E.D. Pa. July 30, 2021) (dismissing defective-design claim in medical-device case when plaintiff did not allege "safer, feasible alternatives in any level of meaningful detail"). Here, as detailed *supra*, Plaintiffs have alleged that Zoetis manufactures Excede with cottonseed oil as a suspension mechanism and that unrefined or improperly refined cottonseed oil contains substances that are toxic to horses. And while an alternative design claim may not be necessary, at this stage Plaintiffs have alleged that both Excede and Naxcel, manufactured by Zoetis and used for the same purpose, are ceftiofur antibiotics, with one requiring additional injections. Based on our reading of the SAC, Plaintiffs have alleged facts sufficient to allow a claim for negligent defective design to survive defendant's motion to dismiss warranting further discovery into that claim.

Accordingly, the motion to dismiss Count II is denied.

2. Count III: Negligent Manufacturing Defect

To plead a viable negligent manufacturing claim, "it is necessary to allege some facts that would plausibly suggest that the manufacturer failed to exercise the reasonable standard of care during the 'manufacturing process.'" *Smith,* 251 F. Supp. 3d at 853. Conclusory allegations that a product was negligently manufactured are not, on their own, sufficient to plead a viable claim. *Id.* (holding that "[w]ithout any factual allegation as to the nature of what went wrong during the manufacturing process, there is no plausible road to recovery for negligent manufacturing.

Defendant moves to dismiss Plaintiffs' negligent manufacturing claim on the grounds that it is insufficient to simply allege, in conclusory fashion, that the product departed from its intended design and contained a manufacturing defect. Plaintiffs allege that Excede was negligently manufactured. Defendant argues Plaintiffs must allege facts that plausibly suggest

how the manufacturer failed to exercise reasonable care during the manufacturing process, and further, must allege factual allegations as to what went wrong during that process. Plaintiffs argue that these matters can be inferred from the pleadings, i.e. that the horse became ill and collapsed immediately after a second Excede injection, and that a reasonable inference is that the batch of that second dose contained a manufacturing defect because "Zoetis ostensibly did not manufacture its product so as to cause sudden death in horses." (ECF No. 25 at 10). More significantly, Plaintiffs have alleged that "[c]ottonseed oil that is not refined or is improperly refined contains substances that are toxic to horses." SAC ¶ 55. Given the standard applicable to motions to dismiss, accepting all factual allegations as true and construing the complaint in the light most favorable to Plaintiffs, Plaintiffs have alleged a defect in the design of the formulation of Excede or the manner in which the formulation was manufactured.

Accordingly, the motion to dismiss Count III is denied.

B. Count IV: Breach of Express Warranty

At Count IV Plaintiffs assert a claim for breach of express warranty. Defendant argues that under Pennsylvania law, an express warranty arises out of the representations or promises of the seller. 13 Pa. Cons. Stat. § 2313; *see also Sowers v. Johnson & Johnson Medical, Inc*., 867 F. Supp. 306, 313 (E.D. Pa. 1994). To create an express warranty, "the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Eiser v. Brown & Williamson Tobacco Corp*., 2006 WL 933394, at *5 (Pa. Super. Ct. Jan. 19, 2006) (quoting *Goodman v. PPG Indus., Inc*., 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004)). To plausibly plead an express warranty claim, some level of meaningful detail is required. *See, e.g., Luke v. Am. Home Prods. Corp.*, 1998 WL 1781624, at *6 (Pa. Ct.

Com. Pl. Nov. 18, 1998) (dismissing express warranty claim because complaint failed to state "what the warranty allegedly covered, when it was made[,] and to whom it was directed").

Here, Plaintiff alleges certain representations made by Zoetis in their labeling, inserts and informational materials, (SAC ¶ 100-113), [3] and that the Plaintiffs and SG's treating veterinarians justifiably relied on such information. (SAC ¶ 109). Plaintiffs further allege: 1) the representations concerning the absence of necrosis, and swelling and edema and that swelling completely resolved within 7 days were made with the insert provided with the bottle of EXCEDE sold herein, (SAC ¶ 102); 2) the insert also included a section on adverse reactions that represented that adverse site reactions resolved in one to twenty days, (SAC ¶ 103); 3) other representations concerning the safety of EXCEDE were made in 2017-2020 via its fast fact sheet, (SAC ¶ 104); and 4) the Owners' equine veterinarians relied upon such statements, labeling, and descriptions regarding the safety of EXCEDE in electing to use EXCEDE on SG, (SAC ¶ 105). Plaintiffs have alleged Zoetis breached its express warranties because Excede does not conform to its statements and representations because an injection of the drug causes serious harm, including death, even when used as recommended and directed by Zoetis. (SAC. ¶¶ 108, 111).

We find that these-fact specific allegations as to the terms of an alleged express warranty state a claim. In order to state a plausible express warranty claim, a complaint "must establish that the seller made an affirmation of fact or a promise to the buyer which relates to the goods and becomes part of the basis of the bargain." *Id.* (quotation and citation omitted). "'A plaintiff

[3]Plaintiffs allege at ¶ 101:
a. "Excede provides peace of mind knowing that the antibiotic has been demonstrated to be safe and effective in horses."
b. "In a safety study, swelling [at the injection site] completely resolved within 7 days in the majority of cases."
c. "Excede makes the treatment process less stressful for you and your horse."
d. "Excede may cause some transient swelling and edema around injection site."
e. "No cases of necrosis, abscess or drainage were reported in the clinical studies."

meets the basis of the bargain requirement by proving that she read, heard, saw or knew of the advertisement containing the affirmation of facts or promise.'" *Id.* (quoting *Kester*, 2010 WL 2696467, at *10); *see also Jeter v. Brown & Williamson Tobacco Corp.,* 113 F. App'x 465, 468 (3d Cir. 2004) (stating that "a plaintiff in a breach of warranty claim must establish that an actual affirmation of fact or a promise formed the basis of the bargain between the seller and the plaintiff. It follows that, in order for an advertisement to form the basis of the bargain, a plaintiff must have seen and relied upon the advertisement" (citing Pa. Cons. Stat. § 2313; *Goodman v. PPG Indus.,* 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004))). Plaintiffs have alleged, inter alia, that "Exceed provides peace of mind knowing that the antibiotic has been demonstrated to be safe and effective in horses," that these statements and other descriptors were a basis of the bargain, the owners and treating veterinarians relied upon these statements and descriptors, and that the express warranty was breached when Zoetis sold goods lacking conformity with their description, i.e. it caused serious harm to horses including death.

We conclude based on the allegations in the SAC that Plaintiffs have plausibly stated a claim upon which relief can be granted, noting that what they "read, heard, saw or knew" of those express warranties was that upon which they relied.

Accordingly, the motion to dismiss Count IV will be denied.

D. Counts V and VI: Misrepresentations

1. Count V: Fraudulent Misrepresentation/Concealment

Allegations of fraud trigger the heightened pleading requirement of Rule 9(b) of the Federal Rules of Civil Procedure. *In re Burlington Coat Factory Sec. Litig.*, 113 F.3d 1410, 1417 (3d Cir. 1997). Rule 9(b) provides, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The purpose of Rule 9(b)

is to "give defendants notice of the claims against them, provide[ ] an increased measure of protection for their reputations, and reduce[ ] the number of frivolous suits brought solely to extract settlements." *In re Supreme Specialties, Inc. Sec. Litig.,* 438 F.3d 256, 270 (3d Cir. 2006).

A complaint alleging fraud "must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004)). Plaintiffs may meet this particularity requirement by supporting their allegations "with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Properties, Inc. Sec. Litig*., 311 F.3d 198, 216 (3d Cir. 2002) (internal quotations omitted). Plaintiffs must "inject[ ] precision and some measure of substantiation into [the] allegations of fraud." *Lum*, 361 F.3d at 224.

Under Pennsylvania law, there are six elements of a fraudulent concealment claim: "(1) an omission; (2) the omission was material to the transaction at hand; (3) the omission was made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) the omission was made with the intent of misleading another into relying on it; (5) the plaintiff justifiably relied on the omission; and (6) the resulting injury was proximately caused by the reliance." *Slippery Rock Area School District v. Tremco, Inc*., 2016 WL 3198122, *8 (W.D. Pa. 2016) (citing *Gaines v. Krawcyzk*, 354 F.Supp.2d 573, 587 (W.D. Pa. 2004)) (citing *Gibbs v. Earnst*, 647 A.2d 882, 889 n.12 (Pa. Super. 1994)). However, mere silence does not constitute concealment sufficient for a finding of fraud if there is no duty to speak. *Wilson v. Donegal Mutual Insurance Co.*, 598 A.2d 1310 (Pa. Super. Ct. 1991).

Here, Plaintiffs allege that the drug was represented as being "safe and effective" and safe for the use of stabled horses. (SAC ¶116). Plaintiffs allege the warning on the Excede bottle in question and the inserts provided therein did not warn of the possibility of death when properly used (SAC ¶ 37), and that the 2013 insert that Excede provided with the product also set forth a section on Adverse Reactions, including injection site swelling, adverse reactions reported in a field study safety analysis, the statistics of edema reported in horses treated with Excede, other side effects, as well as how quickly reactions and side effects were resolved. (SAC ¶ 38). Zoetis failed to disclose that since FDA approval there have been approximately 600 adverse reactions reported, with many including severe reactions and death. (SAC ¶ 39). Plaintiffs allege, *inter alia*:

> 117. Zoetis made such false, misleading and deceptive statements on its label and insert contained with the bottle of EXCEDE as sold to Plaintiffs' veterinarians with the intention of inducing the Owners' equine veterinarians to purchase and/or use EXCEDE, including representing that EXCEDE is safe for use in stabled horses and failing to disclose the danger of death to veterinarians, consumers and end-users with the warnings, inserts and labeling materials provided with the EXCEDE product used herein.
> 118. As averred herein, despite its knowledge of the severely debilitating and/or fatal reactions to the administration of EXCEDE, Zoetis actively concealed the known risks and dangers of EXCEDE to horses and refused to timely revise its warning label, prescribing information, promotional materials and website to reflect the significant negative effects of EXCEDE.
> 119. Zoetis' intentional representations and concealment of the risks and dangers of EXCEDE were material to the transactions consummated by the Owners, their treating equine veterinarians and other end users, namely their purchase and/or use of EXCEDE.
>
> 127. The precise fraudulent misconduct is the failure to include with the EXCEDE product sold herein a warning label or insert that included the warnings regarding death that have been subsequently added to the insert and representing in its fact sheets and insert materials that EXCEDE is safe and that swelling and diarrhea were adverse reactions associated with use of the product when death and other more severe reactions were known to occur.
>
> 128. This fraudulent conduct occurred when the EXCEDE bottle in question was sold

> and from at least 2017-2020 when the inserts, warnings and fact sheets were published and distributed to veterinarians, including Owners' equine veterinarians--despite EXCEDE being aware of significant adverse reactions including death.

We find that these allegations, as to fraudulent misrepresentation or fraudulent concealment, state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice with the necessary specificity to allege a claim sounding in fraud and to further warrant exploration through the discovery process.

Hence, the motion to dismiss Count V will be denied.

2. Count VI: Negligent Misrepresentation

Count VI alleges negligent misrepresentation, in the alternative. Under Pennsylvania law, to prove negligent misrepresentation, a plaintiff must prove: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa.1999) (citing *Gibbs v. Ernst*, 538 Pa. 193, 647 A.2d 882, 890 (Pa.1994)).

Additionally, Rule 9(b) states, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The United States Court of Appeals for the Third Circuit has noted that Rule 9(b) "requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges*." Kester v. Zimmer Holdings, Inc*., Civ. No. 2:10–CV–00523, 2010 WL 2696467, *12 (W.D. Pa. June 16, 2010) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.,* 742 F.2d 786, 791 (3d Cir. 1984)). Although allegations of time, date or place satisfy the

particularity requirements, a plaintiff can also satisfy the pleading requirements by pleading with a "degree of precision or some measure of substantiation into the fraud allegation." *Id.* (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)).

In this case, we find that Plaintiffs have met the pleading requirements. They allege that the veterinarians relied on representations as to the safety of Excede in choosing to administer the product on SG, that defendant knew or should have known of the adverse reactions over a period of time and yet failed to disclose the adverse reactions and deaths to veterinarians, either intentionally, or in the alternative, negligently. The allegations contained in Count VI and the preceding paragraphs of the SAC incorporated by reference place the Defendant on notice of the misconduct at issue.

Therefore, we will deny the motion to dismiss Count VI of Plaintiffs' Second Amended Complaint.

IV. Conclusion

For the reasons stated herein, the Motion to Dismiss will be denied

An appropriate order will be entered.

BY THE COURT:

s/*Robert J. Colville*
Robert J. Colville
United States District Judge

DATED: June 6, 2022

cc/ecf: All counsel of record